

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

March 30, 2023

Commission File Number: 0-29374

EDAP TMS S.A.
Parc Activite La Poudrette Lamartine
4/6 Rue du Dauphine
69120 Vaulx-en-Velin - France

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 30, 2023

EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports Record Fourth Quarter and Full-Year 2022 Results and Announces Leadership Succession Plan to Develop Global Group Strategy

- Record full-year 2022 total revenue of EUR 55.1 million (\$58.0 million) increased 25.1% over full-year 2021
- Full-year HIFU revenue was EUR 15.6 million (USD 16.4 million), an increase of 57.7% as compared to EUR 9.9 million (USD 11.7 million) for the full-year 2021
- Record Q4 2022 total revenue of EUR 15.7 million (\$16.2 million) versus EUR 14.0 million (\$15.9 million) for Q4 2021
- Ended the year with a strong cash position of EUR 63.1 million (\$67.5 million) as of December 31, 2022
- Ryan Rhodes to succeed Marc Oczachowski as Chief Executive Officer of the Company, effective May 1, 2023
- Company to host conference call and webcast today, March 30th, at 8:30 a.m. ET

LYON, France, March 30, 2023 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), a global leader in robotic energy-based therapies, announced today unaudited financial results for the fourth quarter and full-year 2022 and announced a change in its leadership, effective May 1, 2023.

In line with EDAP's Global Group Strategy, and its focus on expansion in the United States and rest of world markets, the Board of Directors has decided to embark on a new era of leadership for the Company. The Board has therefore unanimously appointed Ryan Rhodes Chief Executive Officer of EDAP TMS effective May 1, 2023 to lead, strengthen and accelerate the Company's development. Marc Oczachowski will continue to serve as Chairman of the Board of the Company.

Mr. Rhodes has over 30 years of leadership experience in market development in the medical device industry, including 20 years dedicated to medical robotics. Prior to joining EDAP, he served as Chief Executive Officer of Restoration Robotics, where he led the company to a successful merger with Venus Concept Inc. in 2019. He also held leadership positions at Intuitive Surgical, and Ethicon Inc., a Johnson & Johnson Company.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "In 2022, EDAP delivered another strong year of financial and operational performance, achieving record revenue and more than doubling worldwide Focal One sales compared to 2021. With EDAP experiencing strong positive HIFU momentum, particularly in the U.S., we have now reached a key inflection point to make this transition and to further accelerate our global expansion. I have enjoyed working with Ryan for almost two years. His leadership and knowledge of the industry, combined with his acute understanding of global commercial market development, are excellent assets for EDAP. I have complete confidence in Ryan's ability to continue to accelerate the growth and development of the Company in support of its ongoing strategic objectives."

Ryan Rhodes, Chief Executive Officer of EDAP US, stated, "During the fourth quarter, we achieved a record of nine Focal One transactions in the U.S., reflecting the growing appreciation for the clinical value of Focal One by both large academic healthcare institutions as well as local community hospitals. 2022 was a critical year in the adoption of Focal One robotic HIFU and the growth of this therapeutic option as part of the comprehensive management of prostate cancer. The number of U.S. sites selecting Focal One doubled over the previous year, and we saw positive momentum in the advancement of U.S. society guidelines with focal ablation. Our team and capacity have grown to be well positioned to drive even greater clinical and market expansion in 2023."

Ryan Rhodes added: "I am very pleased to be appointed Chief Executive Officer of the EDAP TMS group, and I am grateful to both Marc and the EDAP Board for their continued confidence in my abilities. I am excited to lead EDAP's global strategy to a new era of growth as we continue to build and expand our winning organization across the U.S. and international markets."

Full-Year 2022 Results

Total revenue for the full year 2022 was EUR 55.1 million (\$58.0 million), representing an increase of 25.1% over full-year 2021 total revenue of EUR 44.1 million (\$51.9 million).

Total revenue in the HIFU business for the full year 2022 was EUR 15.6 million (USD 16.4 million), an increase of 57.7% as compared to EUR 9.9 million (USD 11.7 million) for the full year 2021.

Total revenue in the LITHO business for the full year 2022 was EUR 11.6 million (USD 12.2 million), an increase of 5.0% from EUR 11.0 million (USD 13.0 million) for the full year 2021.

Total revenue in the Distribution business for the full year 2022 was EUR 27.9 million (USD 29.4 million), a 20.6% increase compared to EUR 23.1 million (USD 27.3 million) for the full year 2021.

Gross profit for the twelve months ended December 31, 2022, was EUR 24.2 million (USD 25.4 million), compared to EUR 18.4 million (USD 21.7 million) for the year-ago period. Gross profit margin on net sales was 43.9% for the twelve months ended December 31, 2022, compared to 41.8% for the comparable period in 2021. The increase in gross profit year-over-year was due to higher sales effect on fixed costs, particularly in the HIFU business.

Operating expenses were EUR 28.5 million (USD 29.90 million) for the twelve months ended December 31, 2022, compared to EUR 20.0 million (USD 23.6 million) for the same period in 2021.

Operating loss for the twelve months ended December 31, 2022, was EUR 4.3 million (USD 4.5 million), compared to an operating loss of EUR 1.6 million (USD 1.9 million) for the twelve months ended December 31, 2021.

Net loss for the twelve months ended December 31, 2022, was EUR 2.9 million (USD 3.1 million), or EUR (0.09) per diluted share, as compared to net income of EUR 0.7 million (USD 0.8 million), or EUR 0.02 per diluted share in the year-ago period.

As of December 31, 2022, the company held cash, cash equivalents and short-term investments of EUR 63.1 million (\$67.5 million), as compared to EUR 47.2 million (USD 53.4 million) as of December 31, 2021.

Fourth Quarter 2022 Results

Total revenue for the fourth quarter 2022 was EUR 15.7 million (USD 16.2 million), a 12.8% increase as compared to total revenue of EUR 14.0 million (USD 15.9 million) for the same period in 2021.

Total revenue in the HIFU business for the fourth quarter 2022 was EUR 5.4 million (USD 5.5 million), an increase of 27.9% as compared to EUR 4.2 million (USD 4.8 million) for the fourth quarter of 2021.

Total revenue in the LITHO business for the fourth quarter 2022 was EUR 3.6 million (USD 3.7 million), an increase of 7.5% as compared to EUR 3.3 million (USD 3.8 million) for the fourth quarter of 2021.

Total revenue in the Distribution business for the fourth quarter 2022 was EUR 6.7 million (USD 7.0 million), a 5.0% increase compared to EUR 6.4 million (USD 7.3 million) for the fourth quarter of 2021.

Gross profit for the fourth quarter 2022 was EUR 7.2 million (USD 7.4 million), compared to EUR 6.2 million (USD 7.1 million) for the year-ago period. Gross profit margin on net sales was 45.9% in the fourth quarter of 2022, compared to 44.5% in the year-ago period. The increase in gross profit year-over-year was driven by the higher sales effect on fixed costs.

Operating expenses were EUR 8.8 million (USD 9.1 million) for the fourth quarter of 2022, compared to EUR 5.8 million (USD 6.5 million) for the same period in 2021.

Operating loss for the fourth quarter of 2022 was EUR 1.6 million (USD 1.6 million), compared to an operating profit of EUR 0.5 million (USD 0.5 million) in the fourth quarter of 2021.

Net loss for the fourth quarter of 2022 was EUR 5.1 million (USD 5.3 million), or EUR (0.14) per diluted share, as compared to net income of EUR 1.4 million (USD 1.6 million), or EUR 0.04 per diluted share in the year-ago period.

Conference Call

An accompanying conference call and webcast will be conducted by management to review the results. The call will be held at 8:30 a.m. ET today, March 30th, 2023. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, March 30th, 2023 @ 8:30 a.m. ET

Domestic: 877-451-6152
International: 201-389-0879
Passcode: 13736071
Webcast link: [Here](#)

Following the live call, a replay will be available on the Company's website, www.edap-tms.com under "Investors Information."

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device, EDAP TMS is now the only company offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <http://www.edap-tms.com>, and us.hifu-prostate.com and www.focalone.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 (the "Securities Act") or Section 21E of the U.S. Securities Exchange Act of 1934, which may be identified by words such as "believe," "can," "contemplate," "could," "plan," "intend," "is designed to," "may," "might," "potential," "objective," "target," "project," "predict," "forecast," "ambition," "guideline," "should," "will," "estimate," "expect" and "anticipate," or the negative of these and similar expressions, which reflect our views about future events and financial performance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy and distribution divisions, as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics like the COVID 19 pandemic, or other public health crises, and their related impact on our business operations, including their impacts across our businesses or demand for our devices and services.

Other factors that may cause such a difference may also include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

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EDAP TMS S.A.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 (Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Three Months Ended:		Three Months Ended:	
	December 31, 2022 Euros	December 31, 2021 Euros	December 31, 2022 \$US	December 31, 2021 \$US
Sales of medical equipment	11,493	9,864	11,840	11,231
Net Sales of RPP and Leases	1,441	1,387	1,484	1,579
Sales of spare parts, supplies and Services	2,784	2,720	2,868	3,097
TOTAL NET SALES	15,718	13,971	16,192	15,907
Other revenues	—	1	—	2
TOTAL REVENUES	15,718	13,973	16,192	15,909
Cost of sales	(8,500)	(7,762)	(8,756)	(8,837)
GROSS PROFIT	7,218	6,211	7,436	7,072
Research & development expenses	(1,304)	(562)	(1,344)	(640)
S, G & A expenses	(7,484)	(5,188)	(7,709)	(5,907)
Total operating expenses	(8,788)	(5,750)	(9,053)	(6,547)
OPERATING PROFIT (LOSS)	(1,570)	461	(1,617)	525
Interest (expense) income, net	297	23	306	26
Currency exchange gains (loss), net	(4,075)	786	(4,198)	895
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(5,348)	1,270	(5,509)	1,446
Income tax (expense) credit	217	95	224	108
NET INCOME (LOSS)	(5,130)	1,365	(5,285)	1,554
Earning per share – Basic	(0.14)	0.04	(0.14)	0.05
Average number of shares used in computation of EPS	36,863,623	33,466,136	36,863,623	33,466,136
Earning per share – Diluted	(0.14)	0.04	(0.14)	0.05
Average number of shares used in computation of EPS for positive net income	36,863,623	33,641,317	36,863,623	33,641,317

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average three months' noon buying rate of 1 Euro = 1.0302 USD, and 2021 average three months noon buying rate of 1 Euro = 1.1386 USD

EDAP TMS S.A.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 (Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Year Ended:		Year Ended:	
	December 31, 2022 Euros	December 31, 2021 Euros	December 31, 2022 \$US	December 31, 2021 \$US
Sales of medical equipment	38,462	29,040	40,456	34,229
Net Sales of RPP and Leases	5,617	4,968	5,908	5,856
Sales of spare parts, supplies and Services	11,030	10,052	11,602	11,848
TOTAL NET SALES	55,108	44,060	57,966	51,932
Other revenues	—	6	—	7
TOTAL REVENUES	55,108	44,065	57,966	51,939
Cost of sales	(30,916)	(25,643)	(32,519)	(30,225)
GROSS PROFIT	24,193	18,422	25,447	21,714
Research & development expenses	(4,920)	(3,402)	(5,175)	(4,010)
S, G & A expenses	(23,530)	(16,633)	(24,751)	(19,605)
Total operating expenses	(28,450)	(20,034)	(29,925)	(23,614)
OPERATING PROFIT (LOSS)	(4,257)	(1,612)	(4,478)	(1,900)
Interest (expense) income, net	235	145	248	171
Currency exchange gains (loss), net	1,926	2,360	2,025	2,781
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(2,096)	893	(2,205)	1,052
Income tax (expense) credit	(837)	(193)	(880)	(227)
NET INCOME (LOSS)	(2,933)	700	(3,085)	825
Earning per share – Basic	(0.09)	0.02	(0.09)	0.03
Average number of shares used in computation of EPS	34,392,598	32,129,047	34,392,598	32,129,047
Earning per share – Diluted	(0.09)	0.02	(0.09)	0.03
Average number of shares used in computation of EPS for positive net income	34,392,598	32,422,871	34,392,598	32,422,871

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average twelve months' noon buying rate of 1 Euro = 1.0519 USD, and 2021 average twelve months noon buying rate of 1 Euro = 1.1787 USD

EDAP TMS S.A.
UNAUDITED CONSOLIDATED BALANCE SHEETS HIGHLIGHTS
 (Amounts in thousands of Euros and U.S. Dollars)

	December 31, 2022 Euros	December 31, 2021 Euros	December 31, 2022 \$US	December 31, 2021 \$US
Cash, cash equivalents and short-term treasury investments	63,136	47,183	67,539	53,405
Account receivables, net	14,943	12,118	15,985	13,716
Inventory	11,780	7,499	12,601	8,487
Other current assets	660	581	706	658
TOTAL CURRENT ASSETS	90,518	67,382	96,832	76,267
Property, plant and equipment, net	5,984	5,173	6,401	5,855
Goodwill	2,412	2,412	2,580	2,730
Other non-current assets	2,210	2,260	2,364	2,558
TOTAL ASSETS	101,123	77,226	108,177	87,409
Accounts payable & other accrued liabilities	13,087	10,786	14,000	12,208
Deferred revenues, current portion	4,050	3,408	4,333	3,857
Short term borrowing	1,846	1,914	1,975	2,167
Other current liabilities	2,725	1,843	2,916	2,086
TOTAL CURRENT LIABILITIES	21,708	17,951	23,223	20,318
Obligations under operating and finance leases non-current	1,222	1,318	1,308	1,492
Long term debt, non-current	3,587	4,930	3,837	5,580
Deferred revenues, non-current	264	440	282	498
Other long term liabilities	2,710	2,534	2,899	2,868
TOTAL LIABILITIES	29,492	27,172	31,549	30,755
TOTAL SHAREHOLDERS' EQUITY	71,632	50,054	76,628	56,655
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	101,123	77,226	108,177	87,409

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.0697 USD, on December 31, 2022 and at the noon buying rate of 1 Euro = 1.1319 USD, on December 31, 2021.

EDAP TMS S.A.
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS
 (Amounts in thousands of Euros)

	Year Ended December 31, 2022 (Euros)	Twelve Months Ended December 31, 2021 (Euros)	Year Ended December 31, 2022 (\$US)	Twelve Months Ended December 31, 2021 (\$US)
NET INCOME (LOSS)	(2,933)	700	(3,085)	825
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	4,225	3,225	4,444	3,801
OPERATING CASH FLOW	1,292	3,925	1,359	4,626
Increase/Decrease in operating assets and liabilities	(4,316)	520	(4,539)	613
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(3,024)	4,445	(3,180)	5,239
Short term investments	—	—	—	—
Additions to capitalized assets produced by the company and other capital expenditures	(2,378)	(1,638)	(2,501)	(1,931)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(2,378)	(1,638)	(2,501)	(1,931)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	21,741	20,266	22,869	23,887
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(388)	(585)	(3,053)	(3,992)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	15,952	22,488	14,134	23,204

⁽¹⁾ including share based compensation expenses for 2,103 thousand of Euros for the year ended December 31, 2022 and 1,900 thousand of Euros for the full year ended December 31, 2021.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2022 average twelve months' noon buying rate of 1 Euro = 1.0519 USD, and 2021 average twelve months noon buying rate of 1 Euro = 1.1787 USD



EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
twelve months ended December 31, 2022
(Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items	Total After Consolidation	
Sales of goods	9,437		4,880		24,145		—	38,462	
Sales of RPPs & Leases	4,287		1,058		272		—	5,617	
Sales of spare parts & services	1,909		5,630		3,491		—	11,030	
TOTAL NET SALES	15,634		11,568		27,907		—	55,108	
Other revenues	—		—		—		—	—	
TOTAL REVENUES	15,634		11,568		27,907		—	55,108	
GROSS PROFIT (% of Net Sales)	8,846	56.6%	4,836	41.8%	10,511	37.7%	—	24,193	43.9%
Research & Development	(3,525)		(950)		(444)		—	(4,920)	
Total SG&A plus depreciation	(10,214)		(2,964)		(8,099)		(2,254)	(23,530)	
OPERATING PROFIT (LOSS)	(4,894)		922		1,968		(2,254)	(4,257)	